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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,104	03/19/2007	Valerie Arranz	021305-00294	6158
4372 7590 07/22/2010 ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			EXAMINER DEVI SARVAMANGALA 7N	
			ART UNIT 1645	PAPER NUMBER
			NOTIFICATION DATE 07/22/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
IPMatters@arentfox.com  
Patent\_Mail@arentfox.com

### Office Action Summary

**Application No.**

10/568,104

**Applicant(s)**

ARRANZ, VALERIE

**Examiner**

S. Devi, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 May 2010.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.  
4a) Of the above claim(s) 1-9, 12 and 13 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 10 and 11 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 02/13/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date 082908 & 121407  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Preliminary Amendments**

**1)** Acknowledgment is made of Applicant's preliminary amendments filed 05/04/10, 02/18/10, 11/16/09 and 02/13/06.

### **Election**

**2)** Acknowledgment is made of Applicant's election filed 11/16/09 in response to the lack of unity and the species election requirement mailed 09/16/09. Applicant has elected invention II, claims 10 and 11. Applicant traverses the restriction between inventions II and III. Applicant's traversal is on the grounds that inventions II and III share an antibacterial compound, a covalent link, the same peptide residues and the same relationship between the antibacterial compound and the peptide. Applicant states that the invention of claims 12 and 13 correspond to claims 10 and 11, respectively, providing more detail. Applicant also disagrees with the Office's citation of Avrameas (WO 01/64738 A2) for teaching SEQ ID NO: 27, i.e., Applicant's SEQ ID NO: 1, for transferring or transporting *in vivo* a substance of interest to cells for preparing of a pharmaceutical composition for treating Gram negative infections. Applicant submits that Avrameas does not disclose a peptide which permits the specific integration of an antibacterial agent into Gram negative bacteria cytoplasm.

Applicant's arguments have been carefully considered, but are not persuasive. As set forth previously, claims 10 and 11 are drawn to an antibacterial composition comprising at least a peptide and an antibacterial compound. Such a product was already known in the prior art. For example, see the art rejection below. Claims 12 and 13, as amended, are drawn to a product of the formula recited therein, which includes element 'a' in the formula. Element 'a' however is undefined in the claim. The 'n' is recited to be an integer from 1 to 3, however the recited formula does not contain any 'n'. The products of the amended claims 12 and 13 are different from the product of claims 10 and 11. The above-identified issues add at least an examination burden under 35 U.S.C 112, first and second paragraphs. Therefore, the lack of unity held in the instant application is proper, is hereby maintained, and is made FINAL.

### **Status of Claims**

- 3) Claims 10-13 have been amended via the amendment filed 05/04/10.

Claims 1-13 are pending.

Claims 1-9, 12 and 13 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.

Claims 10 and 11 are under examination.

### **Information Disclosure Statements**

- 4) Acknowledgment is made of Applicant's Information Disclosure Statements filed 08/29/08 and 12/14/07. The information referred to therein has been considered, and an initialed copy is attached to this Office Action.

### **Sequence Listing**

- 5) Acknowledgment is made of Applicants' sequence listing which has been entered on 04/20/07.

### **Priority**

- 6) The instant application is the national stage 371 application of PCT/FR2004/002142, filed 08/13/04, which claims foreign priority to application, 0309962, filed 08/14/2003 in France.

It is noted that a certified copy of the non-English foreign priority document has been submitted in this application. Should Applicant desire to obtain the benefit of foreign priority under 35 U.S.C 119(a)-(d), a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this Office Action. Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

### **Objection(s) to Specification**

- 7) The specification is objected to for the following reason(s):

(A) The instant application is informal in the format or arrangement of the specification. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the Applicants' use.

Content of Specification

- (a) Title of the Invention: See 37 C.F.R. 1.72(a). The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words.
- (b) Cross-References to Related Applications: See 37 C.F.R. 1.78 and M.P.E.P. § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See M.P.E.P. § 310.
- (d) Reference to a "Microfiche Appendix": See 37 C.F.R. 1.96(c) and M.P.E.P. § 608.05. The total number of microfiche and the total number frames should be specified.
- (e) Background of the Invention: The specification should set forth the Background of the Invention in two parts:
  - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
  - (2) Description of the Related Art: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (f) Brief Summary of the Invention: A brief summary or general statement of the invention as set forth in 37 C.F.R. 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (g) Brief Description of the Several Views of the Drawing(s): A reference to and brief description of the drawing(s) as set forth in 37 C.F.R. 1.74.
  - (h) Detailed Description of the Invention: A description of the preferred embodiment(s) of the invention as required in 37 C.F.R. 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. This item may also be titled "Best Mode for Carrying Out the Invention." Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
  - (i) Claim or Claims: See 37 C.F.R. 1.75 and M.P.E.P. § 608.01(m). The claim or claims must commence on separate sheet. (37 C.F.R. 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps.
  - (j) Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 250 words or less on a separate sheet following the claims.
  - (k) Drawings: See 37 C.F.R. 1.81, 1.83-1.85, and M.P.E.P. § 608.02.
  - (l) Sequence Listing: See 37 C.F.R. 1.821-1.825.
- (B) Figures 3 and 5 have panels A-L; Figures 4 and 7 have panels A-C; and Figure 6 has panels A and B. However, the specification does not identify these Figures as such. Amendment to page 12 of the specification is needed. For example, on page 12 of the specification, the limitations 'Figure 3' and 'Figure 5' should be replaced with the limitations -- Figures 3A-3L-- and --Figures 5A-5L-- respectively. Similar changes should be made to the description of Figures 4, 6 and 7.

### **Rejection(s) Under 35 U.S.C. § 112, Second Paragraph**

- 8)** The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

- 9)** Claims 10 and 11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 10 and 11 are indefinite and confusing in the limitations: 'at least one peptide' and 'at least an antibacterial compound' in lines 2 and 3; and the limitations 'one or more ..... peptides'; and 'one or more .... antibacterial compounds' in lines 3-5 of the claims. Are the latter different from or in addition to the former?

(b) Claim 10 is indefinite, incorrect and/or redundant in the limitation 'the said'. See line 6. It is suggested that Applicant delete one of the words.

### **Rejection(s) under 35 U.S.C. § 102**

- 10)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language.

- 11)** Claims 10 and 11 are rejected under 35 U.S.C. § 102(e)(1) as being anticipated by Avrameas *et al.* (US 2003/0199677 A1 – Applicant's IDS) ('677).

Avrameas *et al.* ('677) taught a composition comprising the cell-penetrating peptide, SEQ ID NO: 26, SEQ ID NO: 27, or SEQ ID NO: 46, each carrying an N-terminal cysteine (i.e., spacer arm) that covalently couples the peptide to one substance of interest or some substances of interest such as an antibiotic (i.e., antibacterial compound) for internalization in to cells *in vivo* or *in vitro* and for treating or preventing a disease. A sequence search performed at the Office indicates that the prior art peptide of SEQ ID NO: 26, SEQ ID NO: 27, or SEQ ID NO: 46 has a sequence that is 100% identical in structure to the instantly recited SEQ ID NO: 1. See the

sequence alignments below; and paragraphs [0245], [0244], [0241], [0086], [0068], [0069], [0078], [0079], [0086] and [0151]; and claims 59-61.

US-10-231-889-26

Sequence 26, Application US/10231889

Publication No. US20030199677A1

GENERAL INFORMATION:

APPLICANT: Avrameas, Eustrate

APPLICANT: Ternynck, Therese

TITLE OF INVENTION: Amino Acid Sequences Facilitating Penetration Of A Substance Of Interest

TITLE OF INVENTION: Into Cells And/Or Nuclei

FILE REFERENCE: 20440-001

CURRENT APPLICATION NUMBER: US/10/231,889

CURRENT FILING DATE: 2002-08-29

PRIOR APPLICATION NUMBER: PCT/FR00/02621

PRIOR FILING DATE: 2001-03-01

PRIOR APPLICATION NUMBER: FR00/02621

PRIOR FILING DATE: 2000-03-01

NUMBER OF SEQ ID NOS: 51

SOFTWARE: PatentIn Ver. 2.1

SEQ ID NO 26

LENGTH: 18

TYPE: PRT

US-10-231-889-26

Query Match 100.0%; Score 78; DB 4; Length 18;  
Best Local Similarity 100.0%; Pred. No. 0.0087;  
Matches 16; Conservative 0; Mismatches 0; Indels 0; Gaps 0.

Qy 1 RKKRRRESRKRRRES 16  
| | | | | | | | | | | | | | | |  
Db 3 RKKRRRESRKRRRES 18

US-10-231-889-27

Sequence 27, Application US/10231889

Publication No. US20030199677A1

GENERAL INFORMATION:

APPLICANT: Avrameas, Eustrate

APPLICANT: Ternynck, Therese

TITLE OF INVENTION: Amino Acid Sequences Facilitating Penetration Of A Substance Of Interest

TITLE OF INVENTION: Into Cells And/Or Nuclei

FILE REFERENCE: 20440-001

CURRENT APPLICATION NUMBER: US/10/231,889

CURRENT FILING DATE: 2002-08-29

PRIOR APPLICATION NUMBER: PCT/FR00/02621

PRIOR FILING DATE: 2001-03-01

PRIOR APPLICATION NUMBER: FR00/02621

PRIOR FILING DATE: 2000-03-01

NUMBER OF SEQ ID NOS: 51

SOFTWARE: PatentIn Ver. 2.1

SEQ ID NO 27



LENGTH: 18  
TYPE: PRT  
NAME/KEY: VARIANT  
LOCATION: (1)..(18)  
OTHER INFORMATION: All amino acids are in configuration D  
US-10-231-889-27

Query Match 100.0%; Score 78; DB 4; Length 18;  
Best Local Similarity 100.0%; Pred. No. 0.0087;  
Matches 16; Conservative 0; Mismatches 0; Indels 0; Gaps 0.

Qy 1 RKKRRRESRKKRRRES 16  
|||||  
Db 3 RKKRRRESRKKRRRES 18

US-10-231-889-46

Sequence 46, Application US/10231889  
Publication No. US20030199677A1

GENERAL INFORMATION:

APPLICANT: Avrameas, Eustrate

APPLICANT: Ternynck, Therese

TITLE OF INVENTION: Amino Acid Sequences Facilitating Penetration Of A  
Substance Of Interest

TITLE OF INVENTION: Into Cells And/Or Nuclei

FILE REFERENCE: 20440-001

CURRENT APPLICATION NUMBER: US/10/231,889

CURRENT FILING DATE: 2002-08-29

PRIOR APPLICATION NUMBER: PCT/FR00/02621

PRIOR FILING DATE: 2001-03-01

PRIOR APPLICATION NUMBER: FR00/02621

PRIOR FILING DATE: 2000-03-01

NUMBER OF SEQ ID NOS: 51

SOFTWARE: PatentIn Ver. 2.1

SEQ ID NO 46

LENGTH: 18

TYPE: PRT

NAME/KEY: VARIANT

OTHER INFORMATION: Residue of glycine-phthaloyl in N-terminal position (Xaa)

US-10-231-889-46

Query Match 100.0%; Score 78; DB 4; Length 18;  
Best Local Similarity 100.0%; Pred. No. 0.0087;  
Matches 16; Conservative 0; Mismatches 0; Indels 0; Gaps 0.

Qy 1 RKKRRRESRKKRRRES 16  
|||||  
Db 3 RKKRRRESRKKRRRES 18

Claims 10 and 11 are anticipated by Avrameas *et al.* ('677).

## Remarks

13) Claims 10 and 11 stand rejected.

**13)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**14)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**15)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/  
Primary Examiner  
AU 1645

July, 2010